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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,002	01/14/2003	Jens Bukh	2026-4308US	2099

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,002	Applicant(s) BUKH ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, and 11-18, drawn to isolated nucleic acids encoding the GB virus B, a GB virus B, and methods for the production of the virus.

Group II, claim(s) 9, 10, 39, and 40, drawn to polypeptides of either BG virus B or HCV.

Group III, claim(s) 19-35, drawn to a chimeric GB virus B and viral genome.

Group IV, claim(s) 36-38, drawn to a chimeric HCV including sequences from GB virus B.

For Group II above, the Applicant is additionally required to elect one of the following embodiments. Thus, the Applicant is required to elect an embodiment wherein the polypeptide is a polypeptide from (a) a GB virus B, or (b) an HCV virus.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-III are drawn to GB virus B or nucleic acids, or GBV-B polypeptides, or to chimeric GBV-B particles. The common technical feature of these Groups is the presence of a BG virus B structure. However, the art teaches the GB virus B, and certain polypeptides and nucleic acids therefrom. See e.g., Scarselli et al., J Virol 71: 4985-89. Because the virus and the production of polypeptides thereof were known, and because the inventions are otherwise structurally diverse, the inventions lack unity.

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Group IV lacks unity with Groups I-III because these claims are drawn not to a GB virus B, but chimeric HCV molecules. Because these inventions are drawn to chimeras of a different type of virus, and because the common feature of GB virus B sequences were known in the art (see e.g., Scarselli et al., and WO 95/21922) these inventions lack unity with the inventions of Groups I-III above.

Subgroups (a) and (b) lack unity because each of these groups is drawn to polypeptides from a different virus. The inventions share no common technical feature. Unity is therefore lacking.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Groups III and IV above, the Applicant is required to elect a species wherein the chimeric particle (GB virus, or HCV genome) comprises the following structure from the other virus (GB virus B or HCV):

- (A) the 3' UTR,
- (B) the 5' UTR,
- (C) the complete non-structural sequence,
- (D) a non-structural gene (elect one),
- (E) the complete structural sequence, or
- (F) a structural gene (elect one).

For each of Subgroups (a) and (b) of Group II above, the Applicant is required to elect one of the following species: embodiments wherein the polypeptide is (i) the core protein, (ii) the E1 protein, (iii) the E2 protein, (iv) the NS2 protein, (v) the NS3 protein, (vi) the NS4A protein, (vii) the NS4B protein, (vi) the NS5A protein, or (vii) the NS5B protein from the relevant virus.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claim 19 is generic to species (A) and (B) of Group IV. Claims 20 and 21 correspond to species (A). Claims 22 and 23 correspond to species (B). Claim 24 is generic to species (C) and (D). Claims 25 and 26 correspond to subspecies of (D). Claim 27 is generic to species (E) and (F). Claims 28-32 correspond to subspecies of (F).

The following claim(s) are generic: For Group II, claims 9, 10, 39, and 40.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of species (A)-(F) is drawn to a chimeric particle with a different structure. The inventions therefore share no common special technical feature. Each of species (i)-(vii) is drawn to a different polypeptide, which share no common special technical feature.

Conclusion

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP

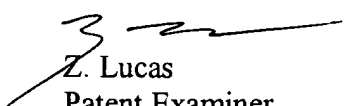
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809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

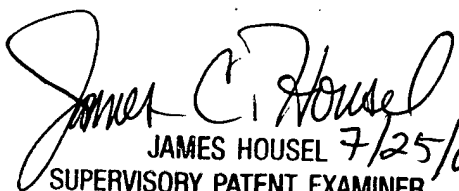
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JAMES HOUSEL 7/25/05
SUPERVISORY PATENT EXAMINER
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